APR 1 0 2001

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K002000 1/2

510(k) Summary of Safety and Effectiveness

RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

Submitter:			**Date of Preparation:** June 28,2000
Company / Institution name: RICHARD WOLF MEDICAL INSTRUMENTS CORP.			**FDA establishment registration number:** 14 184 79
Division name (if applicable): N.A.			**Phone number (include area code):** (847) 913-1113
Street address: 353 Corporate Woods Parkway			**FAX number (include area code):** (847) 913-0924
City: Vernon Hills	**State/Province:** Illinois	**Country:** USA	**ZIP / Postal Code:** 60061
Contact name: Mr. Robert L. Casarsa			
Contact title: Quality Assurance Manager			

Product Information:	
Trade name: Multifunction Suction Irrigation System 4 Multifunction Instrument by Bueß and Melzer	**Model number:** 8285.xxx, 8383.xxx and others
Common name: Modular Suction Irrigation Coagulation Tube	**Classification name:** Coagulation/Suction/Irrigation Tube

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 pre-enactment	1 Combination coagulation suction tube	1 Richard Wolf
2	2 Modular Handles for Irrigation/Suction/Coagulation	2 Karl Storz
3	3 Multi-functional instrument SURGIWAND	3 Auto Suture

1.0 Description

The Multifunction Suction Irrigation System and the Multifunction Instrument by Bueß and Melzer combines a suction and irrigation possibility with HF coagulation opportunity.

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2.0 Intended Use

The **Multifunction Suction Irrigation System** and the **Multifunction Instrument** are used for suction (aspiration) and irrigation via accesses gained by surgery for diagnosis and therapy.

The **HF probes** are for preparation of tissue by means of high frequency current.

3.0 Technological Characteristics

The suction and irrigation is controllable by separate valves. Some of the valves have separate suction/irrigation channels.

An instrument channel with automatic membrane valve allows introducing of auxiliary instruments in some devices.

The multifunction suction irrigation system is a modular system. Various suction/irrigation tubes or HF probes can be combined with the handle or irrigation attachment.

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety or effectiveness as the compared devices. The new technological characteristics have not diminished safety or effectiveness. The submitted devices are substantially equivalent to existing 510(k) devices sold by Richard Wolf, Karl Storz, and Auto Sucture.

5.0 Performance Data

The devices conform to international standards the relevant provisions of the European Device Directive 93/42/EEC.

6.0 Clinical Tests

Clinical tests were not performed.

7.0 Conclusions Drawn

These devices are designed and tested to assure their safety and effectiveness when used according to the instructions manual.

By: Robert L Casarsa Date: June 28, 2000

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 0 2001

Mr. Robert L. Casarsa
Quality Assurance Manager
Richard Wolf Medical Instruments Corp.
353 Corporate Woods Parkway
Vernon Hills, Illinois 60061

Re: K002000
Trade/Device Name: Multifunction Suction Irrigation System and Multifunction Instrument by Buess and Melzer
Regulation Number: 878.4400
Regulatory Class: II
Product Code: GEI
Dated: January 11, 2001
Received: January 12, 2001

Dear Mr. Casarsa:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K002000

Device Name: Multifunction Suction Irrigation System & Multifunction Instrument by Bueß and Melzer.

Intended Use:

The **Multifunction Suction Irrigation System** and the **Multifunction Instrument by Bueß and Melzer** are used for suction (aspiration) and irrigation via accesses gained by surgery for diagnostics and therapy. The **HF probes** are for preparation of tissue by means of high frequency current.

Contraindications:

Contraindications directly related to the product are presently unknown. The attending physician must determine if the planned application is appropriate based on the patient's general condition. Refer to current technical literature for further instructions.

Combinations:

The Instruments are used in connection with endoscopic accessories and auxiliary instruments, e.g. trocar sleeves, forceps, electrodes, as well as HF current devices.

Revised 3/23/01

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K002000

Prescription Use ✓ OR Over-The Counter ____
Per 21 CFR 801.109